

A GUIDE FOR THE
PREPARATION OF RADIOACTIVE
MATERIAL LICENSE APPLICATIONS
FOR MEDICAL PROGRAMS

Radiation Health Branch
Cabinet for Health & Family Services
275 East Main Street
Frankfort, Kentucky 40621

REVISED: APRIL 2005

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I. INTRODUCTION

This guide is intended to provide assistance in the preparation of an application for a specific radioactive material license for possession and use of radioactive material for use in or on human beings.

Usually a single radioactive material license is issued to cover an institution's entire radioisotope program, other than teletherapy. Separate licenses are not issued to different departments of a medical institution, nor are they issued to individuals associated with the hospital.

This guide is intended only for general guidance in preparation of the license application and should not be considered a substitute for the applicant's careful safety evaluation of the proposed use of radiopharmaceuticals and sealed sources. The applicant must ensure that the application correctly and adequately describes the radiation safety measures and procedures to be followed to provide adequate protection.

Please visit our website <http://chfs.ky.gov/dph/radiation.htm> for additional guides, forms and applications. There is also a link to the Kentucky Administrative Regulations.

II. FEES

The applicant should refer to 902 KAR 100:012, Fee Schedule, to determine what fees, if any, should accompany the application. Currently, the fee for a radioactive material license authorizing human use is \$790.00. No action will be taken on applications filed without the proper fee. Checks should be made payable to the Kentucky State Treasurer. Payment of an annual renewal fee is required to renew the license.

A fee is also required when submitting an amendment application to change an existing license, unless the change is the result of a request by the Radiation Health Branch. The current amendment fee is \$75.00 and must accompany the amendment application.

III. FILING AN APPLICATION

An initial application for a license must be filed on Form RPS-7 (Exhibit 1), "Application for Radioactive Material License" and should contain all information specified in the application form. Space provided on the form is limited and additional sheets should be attached as necessary. All items must be described in sufficient detail for the agency to evaluate the radiation safety program.

Two copies of the application should be prepared, each signed and dated in Item 15 by a representative of the institution's management.

The licensee must maintain one (1) copy and will be required to follow the statements set forth in the application, when the license has been issued. The original should be mailed to the Radiation Health Branch, Mail Stop HS 1C-A, 275 East Main Street, Frankfort, Kentucky 40621.

IV. APPLICABLE REGULATIONS

In addition to 902 KAR 100:072, other regulations pertaining to the medical use of radioactive material are found in:

902 KAR 100:010	Definitions
902 KAR 100:012	Fees
902 KAR 100:015	General Requirements
902 KAR 100:019	Standards for Protection Against Radiation
902 KAR 100:021	Disposal of Radioactive Material
902 KAR 100:040	General Provisions for Specific Licenses
902 KAR 100:042	Decommissioning and Financial Surety
902 KAR 100:060	Leak Testing
902 KAR 100:070	Transportation of Radioactive Material
902 KAR 100:165	Notices, Reports, and Instructions to Employees

V. CONTENTS OF AN APPLICATION

Item 1- Applicant's Name and Mailing Address: The applicant must be specified by name and mailing address. For a private practice license, enter the name of the physician or partnership.

Item 2 – Street Address(es) Where Radioactive Material Will be Used: List the address(es) and location(s) where radioactive material will be used or stored if other than the address stated in Item 1. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. The actual location(s) of use must be listed. For example, a post office box number may be suitable for Item 1, but this address does not describe the location of use.

Items 3 and 4 – Self Explanatory

Item 5 – Individual User(s): List the names of all persons who will use, supervise, or direct the use of radioactive material. This list should include the physicians who supervise other physicians in training, and/or who direct technologists or other paramedical personnel who use radioactive material for human or non-human use. Non-physicians may be authorized to use radioactive material for non-human use (e.g., instrument calibration).

Authorized physician-users have the following responsibilities:

- a. The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources.
- b. The prescription of the radiopharmaceutical or source of radiation and amount or dose to be administered.

- c. The determination of the route of administration.

Items a through d may be delegated to physicians who are in training under the supervision of authorized physician users. A licensee that permits supervised activities is responsible for the acts and omissions of the supervised individual.

Properly trained technicians, technologist, or other paramedical personnel under an authorized user's direction may be delegated the following activities:

- a. The preparation and quality control testing of radiopharmaceuticals and sources of radiation.
- b. The measurement of radiopharmaceutical dose prior to administration.
- c. The use of appropriate instrumentation for the collection of data to be used by the physician.
- d. The administration of radiopharmaceuticals and radiation from radioisotopic sources to patients, if permitted under applicable Federal, State, or local laws.

Item 6 – Radiation Protection Officer: State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. If the radiation safety officer (RSO) is not one of the proposed authorized users, submit a complete description of the individuals training and experience using Exhibit 2. The RSO should be a full-time employee of the licensee. **EVEN IF THE LICENSEE EMPLOYS A CONSULTANT TO ACT AS OR ASSIST THE RSO, THE LICENSEE IS STILL RESPONSIBLE FOR THE RADIATION SAFETY PROGRAMS AS REQUIRED BY THE LICENSE.**

Item 7 – Licensed Material: 902 KAR 100:072, Sections 30 and 31 define uses of radiopharmaceuticals in diagnostic and imaging. You may list sections for these radiopharmaceuticals. For radioactive materials not covered in these sections, list each radionuclide to be used, the chemical and physical form, and the maximum quantity in millicuries.

For sealed sources list the manufacture's name, model number, and activity in millicuries. Certain radioactive material sources used for calibration and reference standards are authorized by regulation 902 KAR 100:072, Section 23, and should not be listed.

Describe the intended use for each radionuclide and form listed.

Item 8 – Radiation Detection Instruments: Complete the form contained in Appendix C listing the instrumentation to be available and submit as an attachment to the application. Instruments generally required in a typical nuclear medicine laboratory are:

A. Survey Instruments

- (1) A low-level survey meter, with a thin window of 2 mg/cm^2 , capable of detecting 0.1 milliroentgen per hour to perform contamination surveys.
- (2) A high-level survey meter capable of reading up to 1 roentgen per hour to measure radiation exposure rates that may exist in the vicinity of Mo-99 /Tc-99m generators and therapeutic quantities of radioactive material.

B. Dose calibrators and other instruments to assay radiopharmaceuticals.

C. Instruments used for diagnostic procedures in nuclear medicine (e.g., gamma camera, thyroid probe, well counter, scintillation counter for in vitro studies).

D. Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

Item 9- Calibration: Complete the appropriate portion of the form contained in Appendix D and submit as an attachment to the application for each of the following (as applicable):

A. Survey Instruments. Appendix D, Part A.

B. Dose Calibrator. Appendix D, Part B.

C. Instruments Used for Diagnostic Purposes. Appendix D, Part B.

Item 10 - Personnel Monitoring Devices: Specify the type of personnel monitoring device(s) that will be used (i.e. whole body film badges, ring badges, or thermoluminescence dosimeters) and the names and addresses of the suppliers that may be used. The frequency of change of personnel monitoring devices should be specified. See Appendix O.

Item 11 - Facilities and Equipment: Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) at each location where radioactive material will be used. Include a description of the area(s) assigned for receipt, storage (including waste), preparation, and measurement of radioactive material.

Submit a detailed diagram of the facility, indicating the type, dimensions, position, and thickness of shielding that will be used for:

- A. Use and storage of Tc-99m generators.
- B. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).
- C. Storage of radioactive waste, including decay-in-storage prior to disposal of non-radioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside your department, describe how the material will be secured. Confirm that this area will be surveyed at least weekly.)
- D. Preparation and dispensing of kit radiopharmaceuticals (e.g., lead glass L-block).

Identify adjacent areas across the walls from use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in 902 KAR 100:019, Section 10.

Shielding requirements for the walls, floor, and ceiling should be evaluated for each nuclear medicine room based on total workload (in mCi/week), the energy of radiation, and the presence of patients with activity in the room. Adequate distances should be allowed between technologists and patients being scanned or imaged.

If Xe-133 is to be used, submit a version of your facility diagram that specifies the location and the measured airflow rate of each air exhaust vent and each air supply vent in areas where Xe-133 will be used or stored. (Appendix M describes additional information required for the use of xenon.)

For other facilities in which radioactive material may become airborne, include schematic descriptions of the ventilation system in the diagrams with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Draw diagrams to a specified scale, or indicate dimensions.

Item 12 - Radiation Protection Program:

- A. Radiation Safety Committee/Radiation Safety Officer.

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority. A Radiation Safety Committee must be established by licensees that are authorized two or more different types of uses of radioactive material under 902 KAR 100:072, Sections 33, 37 and 46, or two or more types of units under 902 KAR 100:072, Section 46. If an RSC is not required, you only need to submit the Radiation Safety Officer delegation of authority. See Appendix B.

- B. Personnel Training Program.

Badged Individuals (e.g. technologists) must receive instruction as specified in 902 KAR 100:165, Section 2. Note that many of these items pertain to circumstances at a particular institution; therefore, it may not be assumed that this instruction has

been adequately covered by prior occupational training, Board certification, etc. Outline and submit the program for providing the necessary instruction. Appendix N is a typical training program.

Ancillary personnel (e.g., clerical, nursing, housekeeping, security personnel) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions.

Describe the training that will be provided to all personnel who work with, or in the vicinity of, radioactive materials. Appendix N contains an example of a typical personnel training program.

C. Leak Test

Submit your procedure for leak testing sealed sources. See Appendix P.

D. Procedures for Ordering and Receiving Radioactive Material.

Describe procedures for ordering radioactive material, for receiving material during off duty hours, and for notifying responsible persons upon receipt of radioactive material. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive material ordered for human use is adequately verified upon receipt and checked before use, that radioactive material is secured at all times against unauthorized removal, and that radiation levels in unrestricted areas do not exceed the limits specified in 902 KAR 100:019, Section 10.

Security personnel, nursing personnel, or anyone else who may receive packages during off duty hours should be issued written instructions as to procedures to be followed for (a) receiving, examining, and securing packages and (b) notifying specific personnel (including names and telephone numbers of persons to be contacted) if the package is found or suspected to be leaking and the immediate steps to be taken to prevent spread of contamination.

Appendix E to this guide contains sample procedures and instructions for ordering and receiving packages containing radioactive material. Attach a copy of your procedures.

E. Procedures for Safely Opening Packages Containing Radioactive Material.

Although 902 KAR 100:019, Section 28 (2) exempts certain packages from immediate monitoring, Section 28 (5) requires that each licensee establish procedures for safely opening all packages containing licensed material.

Describe your procedures for examining incoming packages for leakage, contamination, or damage, and for compliance with 902 KAR 100:019. Monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but should, at a minimum, include instructions for (a) surveying packages, (b) wearing gloves while opening packages, (c) checking packing material for contamination after opening, and (d) verifying package contents.

Appendix F to this guide contains a description of an acceptable procedure for safety opening packages.

F. General Rules for the Safe Use of Radioactive Material.

Describe the general instructions to be followed by physicians, radiopharmacists, and technologists while working with radioactive material. The instructions should:

1. Outline control procedures for obtaining permission to use radioactive material at the institution.
2. Explain what laboratory apparel to wear and what equipment to use (e.g., wear laboratory coats and disposable gloves, and use trays and remote handling devices).
3. Prescribe limitations and conditions for handling liquid or loose radioactive materials and the laboratory equipment to be used in working with them. For example, specify which materials and operations should be confined to radiochemical fume hoods or glove boxes.
4. Specify the shielding or remote handling equipment to be used when hard beta and/or gamma-emitting materials are handled. Preparation of radiopharmaceuticals from reagent kits should always be done behind shielding and within appropriate hoods or enclosures. Syringe shields should be used for the routine preparation and administration of patient doses, except on the rare occasions where difficulties in properly administering the dose to the patient would warrant expedited use of lighter syringes. Even in these cases, syringes with the best possible finger protection or remote delivery of the dose (e.g., through use of a butterfly valve) should be used.
5. Give instructions for preparation and assay of patient doses, including instructions to check each therapy dose against the ordering physician's written request.
6. Give instructions concerning movement of material between rooms, in halls, or in corridors, if applicable.
7. Explain requirements for storage of material, labeling of containers, and identification of areas where radioactive material is used. Describe the shielding used for areas where large amounts of radioactive material are stored.
8. Specify personnel monitoring devices to be used, where to obtain them, procedures for properly turning in personnel monitoring devices for processing at appropriate intervals, and instructions for recording exposure results. Also describe where personnel monitoring devices and control dosimeters will be stored to ensure accuracy in monitoring employee occupational exposures and to avoid inadvertent exposure of the devices when they are not being worn.
9. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived). Properly shielded waste receptacles should be employed for used syringes and other radioactive wastes.

10. Describe contamination control procedures, including (1) prohibitions against smoking, eating, drinking, or applying cosmetics in restricted areas, (2) prohibition against storing food, beverages, and personal effects with radioactive material, and (3) instructions for individuals who prepare and administer doses of radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

For certain programs, Appendix G to this guide contains an acceptable set of laboratory rules for the safe use of radioactive material.

G. Unit Dosage Records

Submit your procedure for keeping records of unit dosage use. See Appendix Q.1.

H. Multi-dose Vial Records

Submit your procedure for keeping records of multi-dose vial use. See Appendix Q.2.

I. Contaminant Concentration Records

Submit your procedure for measuring and recording contaminant concentration. See Appendix Q.3 and Q.4.

J. Implant Source Use Records

Submit your procedure for keeping an inventory of implant sources. See Appendix Q.5.

K. Emergency Procedures.

Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used.

A set of emergency procedures acceptable for most programs is contained in Appendix H.

L. Area Survey Procedures.

Describe the routine survey program, including the areas to be surveyed, action levels, and provisions for maintaining records of surveys.

If the application is to cover multiple users and areas of use, the individual user should perform surveys in their own work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in Appendix I.

M. Therapeutic Use of Radiopharmaceuticals.

Describe special precautions for patients treated with radiopharmaceuticals in therapeutic doses. Although some procedures may be performed on an outpatient basis, appropriate procedures should be established because hospitalization is sometimes required.

1. Describe radiation safety procedures directly involved with care of therapy patients, including:
 - (a) Procedures for assigning patients to rooms. Private rooms should be designated for I-131 therapy patients or any other patients that may constitute an internal or external exposure hazard for roommates.
 - (b) Procedures for contamination control in the patient's room (e.g., protective covering for areas of likely contact, use of disposable dishes and utensils, and procedures for posting and controlling radiation areas or potentially contaminated areas).
 - (c) Procedures for surveys of:
 - (1) Areas, equipment, personnel involved in administration of radiopharmaceuticals,
 - (2) Unrestricted areas (i.e., areas adjacent to the patient's room),
 - (3) Linens and other items removed from the patient's room, and
 - (4) The patient's room before it is reassigned to another patient.
 - (d) Records of surveys to be recorded on patient's chart and in radiation safety office records.
 - (e) Instructions to nursing staff (see Exhibit 6).
 - (f) Personnel monitoring procedures for medical and nursing staff.
 - (g) Procedures for disposal of wastes, including:
 - (1) Patient excreta,
 - (2) Surgical dressings, and
 - (3) Other disposable items.
 - (h) Procedures to be followed in case of emergency surgery or death (see NCRP Report Nos. 37 and 48).
 - (i) Procedures for release of patients, including:
 - (1) Criteria for release of patients and
 - (2) Instructions to patients and families.
2. Describe radiation safety procedures involved with all other aspects of therapy procedures, including:
 - (a) Criteria for determining when it is appropriate to use protective facilities, equipment, or supplies (e.g., hoods, shielding blocks, tongs, disposable gloves) and procedures for their use. Personnel should

always wear gloves and work within fume hoods or special enclosures whenever opening vials containing therapeutic quantities of volatile radiopharmaceuticals such as I-131. These hoods should have adequate airflow, and operating procedures should be designed to prevent contamination of personnel and surrounding areas.

- (b) Criteria and procedures for bioassay of personnel. Bioassays should also be considered for personnel (e.g., radiation safety, nursing) who are involved in aspects of therapy procedures. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of I-131 for therapeutic doses. The licensee should measure the thyroid burden of each individual who helped prepare or administer a therapeutic dosage of iodine-131 within three days after administering the dosage. If the burden exceeds 0.04 microcuries of iodine-131, an investigation for the cause and corrective action must be implemented.
- (c) Surveys to limit the spread of contamination and procedures for decontamination. Surveys (e.g., measurement of I-131 in air; measurement of I-131 in the thyroid glands of laboratory personnel; contamination surveys of personnel, equipment, and facilities) should also be performed to determine compliance with 902 KAR 100:072, Section 35.

Submit detailed responses to Items M.1. and M.2. described above. In lieu of submitting a detailed response to Item M.1., you may state that you will follow the procedures in Appendix K.

N. Therapeutic Use of Sealed Sources.

Describe special procedures for patients treated with sealed sources. These procedures should include descriptions of:

1. The areas where sealed sources will be stored, including (1) placement and thickness of shielding, (2) proximity of the storage area to unrestricted areas, and (3) any calculations or measurement data used to check the adequacy of the shielding and other facility protection specifications. Radiation levels in unrestricted areas must be less than 2 millirems in any 1 hour. (902 KAR 100:019, Section 10)
2. Special precautions to be used while handling sealed sources.
3. Your method for determining the radiation doses to the extremities of personnel handling sealed sources.
4. The equipment and shielding available for transporting sources from storage sites to the place of use.
5. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory, and the method for determining that all sources are accounted for and returned to storage immediately following the conclusion of treatment.

6. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument immediately following the conclusion of treatment and before the patient is discharged. This survey should include a source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.
7. Special instructions for nursing care of patients who are treated with sealed sources. (Appendix L to this guide contains a description of procedures to be followed for patients treated with sealed sources.)

O. Air Concentration Control

1. Submit your procedure for estimating worker dose from submersion in noble gases. See Appendix M.
2. Submit your procedure for estimating worker dose from aerosol concentrations. See Appendix M.
3. Submit your procedure for estimating aerosol and gas concentration in effluents. See Appendix M.
4. Submit your procedure for calculating spilled gas clearance times. See Appendix M.

P. Procedures and Precautions for Use of Radioactive Material Specified in Item 7.

Clearly state any additional radiation safety procedures to be followed while individuals are using the material listed in Item 7 (e.g., air sampling, other special surveys, bioassays, leak testing sealed sources, including radiation safety precautions).

Bioassays may be required when individuals work with millicurie quantities of H-3, I-125, or I-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Show in the application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material.

Q. Sealed Source Inventory

Describe the sealed source inventory program. All sealed sources received pursuant to the license shall be inventoried semi-annually (refer to 902 KAR 100:072, Section 24). The physical inventory shall include calibration/reference sources and brachytherapy sources, if authorized by the license. A written record of the inventory shall be maintained and shall include the quantities and kinds of radioactive material, distinctive individual sealed source identity such as model and serial number, location of sources, the date of the inventory and the name of the individual who performed the inventory.

- R. For Mobile Nuclear Medicine Service. See Appendix R.
- S. Procedures for Reporting Medical Events and other reportable occurrences.

Procedures must be commensurate with those in 902 KAR 100:072, Sections 15, 16 and 17.

Item 13 - Training and Experience of Users: Describe the training and experience with regards to radiation protection of authorized users and the Radiation Protection Officer.

- A. Authorized User(s). If the physician is certified by an approved specialty board, submit a copy of the certification. If the physician has been previously authorized to use the radioactive material listed in this application, submit a copy of the license on which the individual is listed as a user.

If the physician has not been previously authorized to use the radioactive material listed, state where he is licensed to practice medicine and submit a complete description of his training and experience on Form RPS-8, Training and Experience/Preceptor Statement form (Exhibit 2). Criteria for acceptable training and experience are contained in Appendix A of this guide.

- B. Radiation Safety Officer. If the radiation safety officer is not one of the physicians named in Item 5, submit a complete description of his training and experience. When a consultant is employed to assist the radiation safety officer, the licensee will be responsible for the proper performance of the radiation safety program as required by the license and the licensee's radiation safety officer will be expected to review the consultant's work and sign the required reports and records. Refer to 902 KAR 100:072, Sections 65 and 68 for training requirements.

Item 14 - Waste Disposal:

Describe specific methods used for disposal of radioactive waste. A licensee may dispose of waste by:

1. Segregation of non-radioactive waste from radioactive waste, decay of radioactive waste in storage until radiation levels have reached background levels in conformance with 902 KAR 100:072, Section 29.
2. Release into a sanitary sewer in conformance with 902 KAR 100:021, Section 3.
3. Release into the air in conformance with 902 KAR 100:019, Section 44.
4. Alternative disposal methods specifically approved by the Cabinet.
5. Transfer to a person or firm properly licensed to receive such waste, (e.g., commercial waste disposal firms).

Complete the form contained in Appendix J to indicate waste disposal methods.

VI. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The licensee must therefore amend the license in accordance with 902 KAR 100:072, Section 5 when appropriate.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

Amendment applications should be signed and dated by a representative of the licensee's administrative management (e.g., the hospital administrator). An original and one copy of the application for amendment should be prepared. The original should be submitted, as in the cases for new or renewal applications, and a copy maintained by the licensee.

VII. RENEWAL OF A LICENSE

Radioactive material licenses are renewed annually by payment of a renewal fee. The renewal fee must be received by the Radiation Health Branch thirty (30) days prior to the expiration date of the license.

APPENDIX A

ACCEPTABLE TRAINING AND EXPERIENCE FOR
MEDICAL USES OF RADIOACTIVE MATERIAL
(902 KAR 100:072, Sections 63 – 78)

General Criteria

Any human use of radioactive material (i.e., the internal or external administration of radioactive material, or the radiation there from, to human beings) must be carried out by or under the supervision of a physician.

902 KAR 100:072 provides that the Cabinet will approve a license application for medical use of radioactive material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (a) basic radioisotope handling techniques and (b) the clinical management of patients to whom radiopharmaceuticals have been administered. Outlined below are training and experience criteria that the Cabinet has found acceptable for physicians who use radiopharmaceuticals.

This training and experience must have been obtained within a 7-year period proceeding the date of the license application or must be supplemented by continuing education or experience. Also, the original training and experience should have been received in a formal residency program in an accredited medical institution. Each physician's training and experience is examined on a case-by-case basis.

A. Training for Routine Diagnostic Procedures (902 KAR 100:072, Sections 69 and 70)

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Sections 30 and 31 in 902 KAR 100:072, a physician must have the following number of hours (hours are in terms of class, laboratory, or clinical experience rather than semester hours) in the topics listed.

1. Imaging and Localization Studies (minimum 700 hours of training and experience)
 - (a) Training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. This training must include laboratory and classroom training in the following areas:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Chemistry of radioactive material for medical use
 - (5) Radiation biology

- (b) Work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is being made, or equivalent involving:
 - (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
 - (3) Calculating, measuring and safely preparing patient dosages
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
 - (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
 - (6) Administering dosages of radioactive drugs to patients or human research subjects
 - (7) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the elute for radionuclidic purity, and processing the elute with reagent kits to prepare labeled radioactive drugs

2. Uptake, Dilution and Excretion Studies (minimum 60 hours of training and experience)

- (a) Training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies. This training should consist of laboratory and classroom instruction in the same topics described in Section A.1.(a) of this appendix.
- (b) Work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is being made, or equivalent.

- (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
- (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
- (3) Calculating, measuring and safely preparing patient dosages
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
- (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
- (6) Administering dosages of radioactive drugs to patients or human research subjects

ALTERNATIVES

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification by an appropriate recognized medical specialty board, or
2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

NOTE:

For physicians who are not certified by a recognized medical specialty board or appropriately identified as an authorized user on another valid license, training and experience must be documented on Form RPS-8, Training and Experience/Preceptor Statement. For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training. Hours of training should be broken down into lecture or laboratory hours or on-the-job training (OJT). OJT must have been obtained in a formalized training program. Be sure that individual hours of training can be traced to the institution where the training was received. Each hour of training should be listed under only one subject category (i.e., the most applicable subject category).

B. Training for Therapy Procedures Involving Radiopharmaceuticals (902 KAR 100:072 Section 71, 72 and 73)

1. The use of unsealed radioactive material for which a written directive is required (minimum of 700 hours of training and experience)

(a) Training in basic radioisotope handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. This training must include classroom and laboratory training in the following areas:

- (1) Radiation physics and instrumentation
- (2) Radiation protection
- (3) Mathematics pertaining to the use and measurement of radioactivity
- (4) Chemistry of radioactive material for medical use
- (5) Radiation biology

(These requirements are in lieu of, not in addition to, those Section A.1.(a) above.)

(b) Work experience under the supervision of an authorized user with experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience must involve:

- (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
- (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
- (3) Calculating, measuring and safely preparing patient dosages
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
- (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures

- (6) Eluting generator systems, measuring and testing the elute for radionuclidic purity, and processing the elute with reagent kits to prepare labeled radioactive drugs
- (7) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
 - (i) Oral administration of less than or equal to 33 mCi of I-131
 - (ii) Oral administration of greater than 33 mCi of I-131
 - (iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV
 - (iv) Parenteral administration of any other radionuclide

2. Oral administration of I-131 requiring a written directive in quantities less than or equal to 33 mCi (minimum of 80 hours of classroom and laboratory training):

- (a) Training applicable to the medical use of I-131 for procedures requiring a written directive:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Chemistry of radioactive material for medical use
 - (5) Radiation biology

(These requirements are in lieu of, not in addition to, those Section A.1.(a) above.)

- (b) Work experience under the supervision of an authorized user with experience in administering dosages in the same dosage category as the individual requesting authorized user status. The work experience must involve:

- (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
 - (3) Calculating, measuring and safely preparing patient dosages
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
 - (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
 - (6) Administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 33 mCi of I-131
3. Oral administration of I-131 requiring a written directive in quantities greater than 33 mCi (minimum of 80 hours of classroom and laboratory training):
 - (a) Training applicable to the medical use of I-131 for procedures requiring a written directive:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Chemistry of radioactive material for medical use
 - (5) Radiation biology
 - (b) Work experience under the supervision of an authorized user with experience in administering dosages in the same dosage category as the individual requesting authorized user status. The work experience must involve:

- (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
- (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
- (3) Calculating, measuring and safely preparing patient dosages
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
- (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
- (6) Administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi of I-131

ALTERNATIVES

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification by an appropriate recognized medical specialty board, or
2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

C. Training for use of manual brachytherapy sources (902 KAR 100:072, Section 74)

1. To qualify as adequately trained to use or directly supervise the use of manual brachytherapy sources, a physician must have:
 - (a) Training in basic radioisotope handling techniques applicable to the use of manual brachytherapy sources. This training must include a minimum of 200 hours of classroom and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation

- (2) Radiation protection
- (3) Mathematics pertaining to the use and measurement of radioactivity
- (4) Radiation biology
- (b) 500 hours of work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is made, or equivalent involving:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) Checking survey meters for proper operation
 - (3) Preparing, implanting, and removing brachytherapy sources
 - (4) Maintaining running inventories of material on hand
 - (5) Using administrative controls to prevent a medical event involving the use of radioactive material
 - (6) Using emergency procedures to control radioactive material.
- (c) 3 years of supervised clinical experience under the supervision of an authorized user as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. Clinical experience may be obtained concurrently with the supervised work experience.

ALTERNATIVES

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification by an appropriate recognized medical specialty board, or
2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

D. Training for ophthalmic use of Sr-90 (902 KAR 100:072, Section 75)

1. To qualify as adequately trained to use or supervise the use of Sr-90 for ophthalmic radiotherapy, a physician must have:
 - (a) 24 hours of classroom and laboratory training applicable to the ophthalmic use of Sr-90. This training must include:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Radiation biology
 - (b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of Sr-90 for the ophthalmic treatment of 5 individuals. This supervised clinical training must involve:
 - (1) Examination of each individual to be treated
 - (2) Calculation of the dose to be administered
 - (3) Administration of the dose
 - (4) Follow up and review of each individual's case history

ALTERNATIVE

In lieu of submitting the above, a physician may be named on a license by submitting a copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

E. Training for use sealed sources for diagnosis (See 902 KAR 100:072, Section 76)

To qualify as adequately trained to use sealed sources for diagnosis, the user shall be a physician, dentist or podiatrist who:

1. Is certified by an appropriate recognized specialty board, or;
2. Has completed eight (8) hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically

applicable to the use of the device. To satisfy the requirement for instruction, the training must include:

- (a) Radiation physics and instrumentation
- (b) Radiation protection
- (c) Mathematics pertaining to the use and measurement of radioactivity
- (d) Radiation biology
- (e) Training in the use of the device for the uses requested

F. Training for use of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units (902 KAR 100:072, Section 77)

1. To qualify as adequately trained to use or directly supervise the use of a sealed source in a therapeutic medical unit, a physician must have:

- (a) Training in basic radioisotope handling techniques applicable to the use of a sealed source in a therapeutic medical unit. This training must include a minimum of 200 hours of classroom and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Radiation biology
- (b) 500 hours of work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is made, or equivalent involving:
 - (1) Reviewing full calibration measurements and periodic spot-checks
 - (2) Preparing treatment plans and calculating treatment doses and times
 - (3) Using administrative controls to prevent a medical event involving the use of radioactive material

- (4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console
 - (5) Checking and using survey meters
 - (6) Selecting the proper dose and how it is to be administered
- (c) 3 years of supervised clinical experience under the supervision of an authorized user as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. Clinical experience may be obtained concurrently with the supervised work experience.

ALTERNATIVES

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification by an appropriate recognized medical specialty board, or
2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

During a two 2-year period after the effective date of October 24, 2005, alternative training and experience requirements will be available. Licensees will have the option of complying with either the training requirements of 902 KAR 100:072, Section 78 or the new requirements in 902 KAR 100:072, Sections 65 through 77 of this chapter. After October 24, 2007, licensee will not have the option of using 902 KAR 100:072, Section 78.

APPENDIX B

MODEL RADIATION SAFETY COMMITTEE CHARTER AND
RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY
(902 KAR 100:072, Section 10)

You may use the following text as it appears here, indicating on your application, 'we will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix B to 'Medical Programs Licensing Guide Revised April 2005.'

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of 902 KAR 100:072.

MODEL CHARTER

Charge. The Committee should:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures
2. Ensure that licensed material is used in compliance with Cabinet regulations and the institutional license
3. Establish a table of investigational levels for individual occupational radiation exposures and implement reasonable steps to maintain personnel exposures as low as possible
4. Ensure that the use of licensed material is consistent with the ALARA philosophy
5. Identify program problems and solutions.

Responsibilities. The Committee should:

1. Be familiar with all pertinent Cabinet regulations, the license application, the license, and amendments
2. Review the training and experience of the proposed authorized users and the Radiation Safety Officer (RSO) to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license
3. Review on the basis of safety and approve or deny, consistent with the limitation of the regulations and the license, all requests for authorization to use radioactive material within the institution

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures
5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;
6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing security, housekeeping, physical plant) are appropriately instructed as required in 902 KAR 100:165.
7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with Cabinet regulations and the conditions of the license, and consistent with the ALARA philosophy. The review should include an examination of records, reports from the RSO, results of Cabinet inspections, written safety procedures, and the adequacy of the management control system;
8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;
9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and
10. Ensure that the radioactive material license is amended, if required, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee should meet as often as necessary to conduct its business but no less than once in each calendar quarter.
2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management is defined as the chief executive officer or that person's delegate or delegates who have authority to provide necessary resources to achieve regulatory compliance. Membership of the radiation safety committee is normally defined by position and not by name. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)
3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, should be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the Radiation Health Branch, Frankfort, KY at anytime.

Signature of Management

I accept the above responsibilities.

Signature of the Radiation Safety Officer

APPENDIX C

INSTRUMENTATION

A. Survey meters:

- a. Manufacturer's name: _____
 Manufacturer's model number: _____
 Number of instruments available: _____
 Minimum range: _____ mR/hr to _____ mR/hr
 Maximum range: _____ mR/hr to _____ mR/hr
- b. Manufacturer's name: _____
 Manufacturer's model number: _____
 Number of instruments available: _____
 Minimum range: _____ mR/hr to _____ mR/hr
 Maximum range: _____ mR/hr to _____ mR/hr

B. Dose calibrator:

Manufacturer's name: _____
 Manufacturer's model number: _____
 Number of instruments available: _____

C. Instruments used for diagnostic procedures:

Type of Instrument	Manufacturer's Name	Model No.
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- D. Other (e.g., liquid scintillation counter, area monitor, velometer) including instrumentation used for counting contamination swipes:

APPENDIX D
PART A

CALIBRATION OF SURVEY INSTRUMENTS
(902 KAR 100:072, Section 21)

Check appropriate items.

1. Survey instruments will be calibrated before first use, annually and following a repair that may affect the calibration of the instrument.
 - a) Calibrate all scales with readings up to 1 R/hr
 - b) Calibration will be performed at two separate readings on each scale or decade used for radiation protection purposes
 - c) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration
2. After checking the battery, survey instruments in use should be checked using the dedicated check source daily prior to use. If the indicated exposure rate and the calculated exposure rate differ by more than 20%, do not use the instrument.
3. Survey instruments will be calibrated:
 - a. By the manufacturer.
 - b. At the licensee's facility.

- (1) Calibration source

Manufacturer's name _____

Model no. _____

Activity in millicuries _____

or

Exposure rate at a specified distance _____

Accuracy _____

Traceability to primary standard _____

- (2) The step-by-step procedures, including radiation safety procedures, are attached.

c. By a consultant or outside firm

- (1) Name _____
(2) Location _____
(3) Procedures and sources

_____ have been approved by an Agreement State or the U.S. NRC. A copy of the license, the procedures, and a description of the sources are attached. The calibration report will contain the information on

- the attached “Certificate of Instrument Calibration.”
- the consultant’s reporting form as attached.

_____ are described in the attachment, and the consultant’s report will contain the information on

- the attached “Certificate of Instrument Calibration.”
- the consultant’s reporting form as attached.

4. Records demonstrating that the licensee has complied with the procedures indicated above in Items 1 through 3 shall be maintained for 3 years for inspection by the Cabinet for Health and Family Services.

SAMPLE CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

	Exposure rate	Instrument reading	Exposure rate	Instrument reading	Exposure rate	Instrument reading
Scale	(mR/hr)	(mR/hr)	(mR/hr)	(mR/hr)	(mR/hr)	(mR/hr)

Comments:

	Activity or Exposure Rate at Specified Distance	Calibration Accuracy
<u>Nuclide</u>		

Calibration
Source:

Calibrated by _____ Date _____

APPENDIX D
PART B

GUIDE FOR THE PROPER USE OF DOSE CALIBRATORS (if applicable)

1. If a dose calibrator is used as the means by which to determine the activity of each dosage, radiopharmaceuticals will be assayed for activity to an accuracy of ± 10 percent of the true value prior to being administered to patients. Such assays shall be performed using the dose calibrator listed in response to item 8 of this application.
2. The dose calibrator shall be checked for accurate operation using the manufacturer's instructions or nationally recognized standards, an example of which can be found below.
3. Complete the table below listing sealed sources used for dose calibrator quality assurance.

Instrument Constancy

Manufacturer	Model	Nuclide	Activity (mCi)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Instrument Accuracy*

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

- * Sources used for instrument accuracy shall have been calibrated by comparisons with standard sources that have been assayed by NBS. State in activity (above) the calibration accuracy. Documentation of this source calibration shall be maintained by the licensee.

4. Quality control and maintenance of instrumentation used for diagnostic procedures shall be performed routinely in accordance with the manufacturer's recommendations. (Attach a copy of such procedures.)
5. Records demonstrating the licensee has complied with the procedures indicated in Items 1 - 4 shall be maintained for inspection by the Cabinet for Health & Family Services.

SAMPLE STANDARDS FOR DOSE CALIBRATOR QUALITY ASSURANCE

Test for the following:

1. Instrument constancy (at installation and daily prior to use thereafter).
2. Instrument accuracy (at installation and at intervals not to exceed 12 months thereafter).
3. Instrument linearity (at installation and at intervals not to exceed 3 months thereafter).
4. Geometrical variation (at installation).
5. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

After repair, adjustment, or relocation of the dose calibrator, repeat all the appropriate tests.

Test for Instrument Constancy

Assay one relatively long-lived reference source, such as Cs-137 or Co-57, using a reproducible geometry before each day's use of the instrument. The source shall have an activity of at least 50 microcuries of a photon-emitting radionuclide with a half-life greater than 90 days.

1. Assay the source using a frequently used setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semi-log paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the \pm percent limits on the graph.

7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ± 10 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

Test of Instrument Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8 a.m.
2. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.
3. Convert the time and date information you recorded to hours elapsed since the first assay.
4. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.
5. Draw a 'best fit' straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. $(A_{\text{observed}} - A_{\text{line}}) / (A_{\text{line}}) = \text{deviation}$.
6. If the worst deviation is more than ± 10 percent, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
7. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of “sleeves” of various thicknesses to test for linearity, it will first be necessary to calibrate them.

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes.
2. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
3. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
4. Continue for all sleeves.
5. Complete the decay method linearity test steps 2 through 7 above.
6. From the graph made in step 4 of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the “equivalent decay time” for sleeve 1. Record that time with the data recorded in step 2.
7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the “equivalent decay time” for sleeve 1. Record that time with the data recorded in step 2.
8. Continue for all sleeves.
9. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
2. Steps 3 through 5 below must be completed within 6 minutes.
3. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
4. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
5. Continue for all sleeves.
6. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the

graph, note the date and the model number and serial number of the dose calibrator.

7. Plot the data using the equivalent decay time associated with each sleeve.
8. Draw a “best fit” straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. $(A=\text{observed} - A\text{-line})/A\text{-line} = \text{deviation}$.
9. If the worst deviation is more than ± 10 percent, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to “true activity.”
10. Put a sticker on the dose calibrator that says when the next linearity test is due.

Test for Geometrical Dependence

Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cc plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
2. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated.
3. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
4. Repeat the process until you have assayed a 2.0-cc volume.
5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen “standard volume.”
6. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from “indicated activity” to “true activity.” If this is necessary, be sure to label the table or graph “syringe geometry

dependence,” and note the date of the test and the model number and serial number of the calibrator.

7. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
8. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
9. Repeat the process until you have assayed a 19 cc volume. The entire process must be completed within 10 minutes.
10. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen “standard volume.”
11. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from “indicated activity” to “true activity.” If this is necessary, be sure to label the table or graph “vial geometry dependence,” and note the date of the test and the model number and serial number of the calibrator.

Test for Instrument Accuracy

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.
2. Repeat step 1 for a total of 3 determinations, and average results.
3. The average activity determined in step 2 should agree with the certified activity of the reference source within ± 5 percent after decay corrections.
4. Repeat the above steps for the commonly used radionuclides for which adequate reference standards are available.
5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ± 10 percent indicate that the instrument must be repaired or adjusted.
7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL (902 KAR 100:019 and 040)

1. The Supervisory Nuclear Medicine Technologist or chief nuclear medicine physician will place all orders for radioactive material and will ensure that the requested material and quantities are authorized by the license and that possession limits are not exceeded.
2. A system for ordering and receiving radioactive material will be established and maintained. The system will consist minimally of the following:
 - a. Ordering of routinely used material
 - (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
 - (2) The written records will be referenced when opening or storing radioactive shipment.
 - b. Ordering of specially used material (e.g., therapeutic uses):
 - (1) A written request will be obtained from the physician who will perform the procedure.
 - (2) Persons ordering the material will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
 - (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
 - c. It is essential that written records be maintained for all ordering and receipt procedures.
3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the written procedures for ordering and receiving radioactive material.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL (902 KAR 100:019, Section 28)

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the quantity limits as specified in 902 KAR 100:019, Section 28. They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of 902 KAR 100:019, Section 28. All shipments of liquids greater than exempt quantities will be tested for leakage. The Cabinet will be notified in accordance with the regulations if removable contamination exceeds 0.001 microcurie (2,200dpm)/100 cm² or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1m).
2. For all packages, the following additional procedures for opening packages will be carried out:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
 - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The “transport index” noted on packages with “Yellow II” or “Yellow III” labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface; the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with “White I” labels should be less than 0.5 millirem per hour at the package surface. (See 172.403 of 49 CFR Part 172.)
 - d. Open the package with the following precautionary steps:
 - (1) Open the outer package (following manufacturer’s directions, if supplied) and remove packing slip.
 - (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle. [In the case of special orders (e.g., therapy doses), also compare with physician’s written request.]
 - (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
 - (4) Check also that shipment does not exceed possession limits.
 - e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity (e.g. dpm/100 cm² etc.). The licensee should specify in the procedure manual which instrument (for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter) should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per

- minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.
- f. Check the user request to ensure that the material received is the material that was ordered.
 - g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.
 - (1) If contaminated, treat this material as radioactive waste.
 - (2) If not contaminated, remove or obliterate the radiation labels before discarding in regular trash.
 - h. Make a record of the receipt.
3. For packages received under the general license in 902 KAR 100:050 the following procedure for opening each package will be followed:
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
 - b. Check to ensure that the material received is the material that was ordered. See Exhibit 5 for a sample record form you may want to use.

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposal gloves at all times while handling radioactive materials.
3. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
5.
 - a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
 - b. Do not store food, drink, or personal effects with radioactive material.
6.
 - a. Perform dose determination prior to administration. This may be accomplished by either of the methods described in 902 KAR 100:072, Section 22. Do not use any doses that differ from the prescribed dose by 20 percent or more.
 - b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.
7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.
8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals. Ring badges should be worn toward the palm side of the hand for measuring hand exposure.
9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.
10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate in accordance with survey procedures.
12. Confine radioactive solutions in covered containers that are plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
13. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
14. Sources with even a small amounts of radioactivity can exhibit a high dose rate on contact, therefore you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.
15. Use remote handling devices (tongs) when working with radioactive material.

APPENDIX H

EMERGENCY PROCEDURES

You may use the following model spill procedures as they appear here, indicating on your application, “We will establish and implement the model spill procedures published in Appendix H to Medical Program Licensing Guide, Revised April 2005.”

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing and shoes for contamination.
5. Report incident to the Radiation Safety Officer (RSO).
6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 3) and the Radioactive Spill Contamination Survey (see Exhibit 4).

Major Spills of Liquids and Solids

1. Clear the area. Notify persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible, but only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the Radiation Safety Officer immediately.

RADIATION SAFETY OFFICER: _____
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATIVE NAMES AND TELEPHONE NUMBERS DESIGNATED BY
RADIATION SAFETY OFFICER: _____

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 3) and the Radioactive Spill Contamination Survey (see Exhibit 4).

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

Table 1, which may be used as general guidance to determine whether a major spill procedure for a minor spill procedure should be implemented, was developed based on a comparison of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values)., 51 FR 1092.
2. "Gamma Radiation Levels for One Curie of Some Radionuclides," Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.
3. National Council on Radiation Protection and Measurements, "Safe Handling of Radioactive Materials," NCRP Report No. 30, Paragraph 2.3 and Table 2, 1964.
4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40 and 70, 46 FR 29712, Table 1, June 3, 1981.

Table 1 may need to be modified before being used for guidance in a specific area of use.

TABLE H-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor. .

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:.

6 pairs disposable gloves, 1 pair housekeeping gloves
 2 disposable lab coats
 2 paper hats
 2 pairs shoe covers
 1 roll absorbent paper with plastic backing
 6 plastic trash bags with twist ties
 "Radioactive Material" labeling tape
 1 china pencil or marking pen
 3 prestrung "Radioactive Material" labeling tags
 Supplies for 10 contamination wipe samples
 Instructions for "Emergency Procedures"
 Clipboard with one copy of Radioactive Spill Report Form
 Pencil

Forms

You may want to use Exhibit 3, Radioactive Spill Report, and Exhibit 4, Radioactive Spill Contamination Survey Forms.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

If personnel involved in the surgical procedure are likely to receive exposures exceeding the non-occupational permissible dose limits specified in 902 KAR 100:019, Section 10, the following procedures will be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-31 sodium iodine, fluids (e.g., blood, urine, etc.) will be carefully removed and contained in a closed system.
2. The surgeon and the personnel involved in the surgical procedures will wear protective gear for the protection of the eyes from splashing of foreign materials, as well as from beta radiation.
3. The RSO will direct personnel in methods to keep doses as low as reasonably achievable during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced in the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

If personnel involved in the autopsy are likely to receive exposures exceeding the non-occupational permissible dose limits specified in 902 KAR 100:019, Section 10, the following procedures will be followed:

1. Upon the death of the therapy patient, the authorized user in charge and the RSO will be notified immediately.
2. An autopsy will be performed only after consultation and permission from the RSO.
3. Protective eyewear will be worn by the pathologist and his assistants for protection from possible splashing of foreign materials and exposure from beta radiation.
4. If an entire block of tissue containing the radionuclide can be removed during autopsy, this will be done first. The remainder of the autopsy can then proceed as usual.
5. The RSO will evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses as low as reasonably achievable during the autopsy.
6. When possible, separate organs will be promptly removed from the body, and detailed dissection will be carried out a safe distance away from the body.
7. After selected small samples have been removed, the radioactive tissues that are retained will promptly be placed in appropriately shielded vessels for storage or disposed according to procedures deemed appropriate by the RSO and in accordance with the regulations.
8. If an injury occurs during the autopsy which results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced in the wound. The RSO will be informed of any possible radiation hazard.

APPENDIX I
AREA SURVEY PROCEDURES
(902 KAR 100:072, Sections 26, 28, 29, 35, 38, 47, 59)
(902 KAR 100:019, Section 12)

Each licensee shall conduct the following surveys as applicable with instruments and equipment that are properly calibrated for the radiation to be measured:

- At the end of each day of use, survey all areas where I-131 in quantities greater than 30 microcuries or any other therapeutic dosage of unsealed radioactive material, has been used or administered
- Licensees providing mobile medical service shall survey all areas of use before leaving a client's address
- Immediately after implanting sources and immediately after removing sources, surveys should be conducted to confirm expected results
- After use of a remote afterloader, survey patient and unit to confirm expected results prior to releasing patient
- Survey the main source safe with sources in the shielded position to ensure maximum and average radiation levels do not exceed levels stated in the Sealed Source & Device Registry anytime a source is added, shielding may have been reduced, or there is reason for concern that the radiation safety of the unit may have been compromised. Maintain records for the duration of the unit
- Prior to opening any packages containing radioactive material (see appendix F)
- Prior to disposal of waste held for decay-in-storage, survey the surface to ensure that radioactivity cannot be distinguished from the background radiation level
- Any material removed from the room of a patient who cannot be released under 902 KAR 100:072, section 27, unless handled as radioactive waste, shall be surveyed to ensure that radioactivity cannot be distinguished from the background radiation level
- Conduct any survey, reasonable under the circumstances, to evaluate the extent of radiation levels, concentrations or quantities of radioactive material, and potential radiological hazards that may be present IAW 902 KAR 100:019.

Information required on each survey record includes, but is not limited to:

- Date of the survey
- Results of the survey
- Instrument used to conduct the survey
- Name of the individual who performed the survey

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

____ In the sanitary sewer system in accordance with 902 KAR 100:021, Section 3.

____ By commercial waste disposal service (see also Item 4 below).

____ Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

____ Returned to the manufacturer for disposal.

____ Held for decay for ten (10) half lives and radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. Be sure that waste storage areas were described in your application. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash. These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

____ Disposed of by commercial waste disposal service (see Item 4).

____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

____ Held for decay for ten (10) half lives and radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

____ Disposed of by commercial waste disposal service (see Item 4).

____ Other (specify): _____

4. The commercial waste disposal service used will be

(Name) (City, State)

NRC/Agreement State License No. _____

5. For each waste disposal method indicated above, submit a step-by-step procedure instructing employees in the disposal method. Such procedures should describe the controls used to ensure regulatory limits are not exceeded. Refer to 902 KAR 100:021, Section 3 (sanitary sewer releases) and 902 KAR 100:019 (airborne releases and effluent releases) if necessary.

APPENDIX K

MODEL PROCEDURES FOR THE SAFE USE OF RADIOPHARMACEUTICALS IN THERAPY (902 KAR 100:072, Sections 27, 34 and 35)

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may indicate on your application, “We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix K to Medical Programs Licensing Guide, Revised April 2005.”

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:072, Sections 27, 34, and 35.

MODEL PROCEDURE

1. The patient’s room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.
2. Prepare the room for the procedure as follows:
 - a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, doorknobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.
 - b. Prepare separate boxes for linen, disposable waste, and non-disposable contaminated items. Place a single large resealable plastic bag in each box, or supply several small plastic bags.
 - c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.
 - (1) Containers should be unbreakable and resealable.
 - (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.
 - (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper.
 - (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

- (5) Supply a wide-mouth anti-splash funnel.
- d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.
3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
4. Supply the nurses with film badges or TLDs.
5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131, Phosphorus-32, or Gold-198" (Exhibit 6), or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.
6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
7. Only those persons needed for medical, safety, or training purposes should be present during the administration.
8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.
9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in 902 KAR 100:019, Section 10). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter sign out form. Post the room with a "Radioactive Materials" sign.
10. For patients treated with liquid or gelatin-capsuled I-131, within 3 days after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also, consider a thyroid burden assay for patient care personnel after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.
11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
12. Do not release any patient until either the exposure rate from the patient is less than 7 millirem per hour at 1 meter or the retained radioactivity is less than 33 millicuries. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.
13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

- a. Remove all absorbent paper, and place it in the appropriate container.
- b. Transfer all containers to a decay-in-storage or decontamination area.
- c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm².
- d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Exhibit 7, “Radiation Safety Checklist for Iodine Therapy over 33 Millicuries,” may also be helpful to you.

APPENDIX L

MODEL PROCEDURE FOR THERAPEUTIC USE OF SEALED SOURCES (902 KAR 100:072, Sections 27 39, 40 and 41)

You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, you may indicate on your application, “We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix L to “Medical Programs Licensing Guide, Revised April 2005.”

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:019, Section 10, and 100:072, Sections 27, 39, 40 and 41.

You may find a checklist to be helpful, such as Exhibit 8, “Radiation Safety Checklist for Temporary Implant Therapy.”

MODEL PROCEDURE

1. The patient’s room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in 902 KAR 100:019, Section 10.
2. Supply the nurses with film badges or TLDs.
3. Brief the nurses on radiation safety precautions. Use the sample form, “Nursing Instructions for Patients Treated with Temporary Implant Sources,” Exhibit 9, or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing.
4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.
5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.
6. Mark a visitors’ “safe line” on the floor with tape as far from the patient as possible.
7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors’ “safe line,” and in the surrounding hallways and rooms (the last rates must conform to requirements in 902 KAR 100:019, Section 10. Record this and any other necessary information on the nursing instruction form or the nurses’ dosimeter sign out form. Post the room with a “Radioactive Materials” sign.
8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources.

Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 7 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

You may want to use the sample forms in Exhibit 8, "Radiation Safety Checklist for Temporary Implant Therapy," and Exhibit 9, "Nursing instructions for Patients Treated with Temporary Implant Sources."

APPENDIX M

MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS (902 KAR 100:019, Section 44)

If a disposable, single use, unit dose system of administration is used, the following does not apply. If any other method of administration of gasses or aerosols is used, additional precautions may be necessary. The following procedures are provided as a guide.

WORKER DOSE FROM NOBLE GASES (Item M.1)

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to Item M.1 by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item M.1 by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix M to -"Medical Programs Licensing Guide, Revised April 2005."

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. If you will follow the model procedure below for calculating worker dose from noble gases, you may respond to Item M.1 by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix M to "Medical Programs licensing Guide, Revised April 2005."

If none of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 902 KAR 100:019, Section 44.

WORKER DOSE FROM AEROSOLS (Item M.2)

If you will collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the manufacturer's instructions for checking for accuracy and constancy, you may respond to Item M.2 by saying, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. If you will follow the model procedure below for calculating worker dose from aerosols, you may respond to Item M.2 by saying, “We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix M to “Medical Programs Licensing Guide, Revised April 2005.”

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 902 KAR 100:019, Section 44.

M.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Collect the following data:
 - a. Estimated number of studies per week;
 - b. Activity to be administered per study;
 - c. Estimated activity lost to the work areas per study (you may assume 20 percent loss);
 - d. Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);
 - e. Measured airflow exhausted by each vent in the imaging room (the exhaust should be vented and not recirculated within the facility);
 - f. Measured airflow exhaust at the storage site (e.g., a fume hood); and
 - g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} uCi/ml in restricted areas and 5×10^{-7} uCi/ml in unrestricted areas. For soluble Tc-99m, the maximum permissible values are 7×10^{-5} uCi/ml in restricted areas and 2×10^{-7} uCi/ml in unrestricted areas. For other gases or aerosols, see 902 KAR 100:019, Section 44.
2. The following calculations must be made:
 - a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
 - b. The estimated average concentration in restricted areas.

- (1) The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.
- (2) If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)

M.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.
2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

M.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.
2. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.
3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.
4. Follow the trap manufacturer's instructions for replacing the trap.

PUBLIC DOSE FROM AIRBORNE EFFLUENT (Item M.3)

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value in 902 KAR 100:019, Section 44.

If you are not directly venting aerosols and gases to the atmosphere, you may respond to Item M.3 by saying, “We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.”

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. If you will follow the model procedure below for calculating release concentrations, you may respond to Item M.3 by saying, “We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix M to “Medical Programs Licensing Guide, Revised April 2005.”

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 902 KAR 100:019, Section 44.

SPILL GAS CLEARANCE TIME (Item M.4)

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix M.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item M.4 by saying, “We will calculate spilled gas clearance times according to the procedure that was published in Appendix M.4 to ‘Medical Programs Licensing Guide, Revised April 2005.’”

You may develop your own procedure for review. If you do so, you should consider all the above information.

M.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:

- a. A, the highest activity of gas in a single container, in microcuries;
- b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;

- c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;
- d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} uCi/ml in restricted areas and 5×10^{-7} uCi/ml in unrestricted areas. For other gases, see 902 KAR 100:019.
- e. V, the volume of the room in milliliters.

2. For each room make the following calculations:

- a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
- b. The evacuation time $t = \frac{-V}{Q} \times \ln(C \times V/A)$.

APPENDIX N

PERSONNEL TRAINING PROGRAM

All personnel working with, or in the vicinity of radioactive material will receive proper instruction, appropriate to their activities. Personnel include radiation workers, clerical, nursing, housekeeping, security and others. Training will be provided in the form of lectures, formal course work, and demonstrations appropriate to the subject covered.

Personnel will be properly instructed:

- a. Before assuming duties with, or in the vicinity of radioactive materials.
- b. During annual refresher training.
- c. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction to personnel will include the following subjects:

- a. All terms of the license pertinent to their duties.
- b. Areas where radioactive material is used or stored.
- c. Potential hazards associated with radioactive material in each area where the employees work.
- d. Radiological safety procedures appropriate to their respective duties.
- e. Pertinent Kentucky Administrative Regulations, 902 KAR 100.
- f. Licensee's in-house work rules.
- g. Obligation to report unsafe conditions to the radiation safety officer.
- h. Appropriate response to emergencies or unsafe conditions.
- i. Right to be informed of their radiation exposure and bioassay results.
- j. Locations where the licensee has posted, or made available, notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 902 KAR 100:165.

APPENDIX O

MODEL PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM (902 KAR 100:019, Section 13)

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may indicate on your application, “We will establish and Implement the model personnel external exposure monitoring program published in Appendix O ‘Medical Programs Licensing Guide, Revised April 2005.’”

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of 902 KAR 100:019, Section 13.

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).
2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a regular basis.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.
4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.
5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages, will not normally be issued exposure monitors.

APPENDIX P

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES (902 KAR 100:072, Section 24)

You or your consultant may use the following model procedure to leak-test sealed sources. If you, or the consultant, follow the model procedure you may indicate on your application, “We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix P to ‘Medical Programs Licensing Guide, Revised April 2005.’”

You may develop your own procedure for review. If you do, you should consider for inclusion all the features in the model and carefully review the requirements of 902 KAR 100:072, Section 24.

MODEL PROGRAM

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form. (See 902 KAR 100:072, Section 24(6) for exemptions)
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
 - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
 - b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
 - c. If you are testing radium sources at the same time you are testing other licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.
4. The samples will be analyzed as follows:
 - a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

- b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.
- c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
- d. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
- e. Continue the same analysis procedure for all wipe samples.
- f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. File a report to the Cabinet within 5 days in accordance with 902 KAR 100:072, Section 18
- g. Sign and date the list of sources, data, and calculations.

APPENDIX Q

RECORDS OF RADIOACTIVE MATERIAL USE (902 KAR 100:072, Sections 22, 32 & 39 and 100:042, Section 11)

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multi-dose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

Q.1 Records of Unit Dosage Use (902 KAR 100:072, Section 22)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may indicate on your application, “We will establish and Implement the model procedure for a unit dosage record system that was published in Appendix Q.1 to ‘Medical Programs Licensing Guide, Revised April 2005.’”

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:072, Section 22.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radiopharmaceutical;
2. Date of receipt;
3. Supplier;
4. Lot number or control number, if assigned;
5. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
6. Date of administration or disposal;
7. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual),

- b. Measured activity in millicuries or microcuries and date and time of measurement, if using a dose calibrator,
 - c. Patient name and identification number if one has been assigned;
- 8. If discarded, the date and method of disposal; and
- 9. Initials of the individual who made the record.

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Q.2 Records of Multi-dose Vial Use (902 KAR 100:072, Section 22)

You may use the following model procedure to keep a record of multi-dose vial use. If you will follow the model procedure, you may indicate on your application, 'We will establish and implement the model, procedure for a multi-dose vial record system that was published in Appendix Q.2 to 'Medical Programs Licensing Guide, Revised April 2005.'

If you prefer, you may develop your own multi-dose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of 902 KAR 100:072, Section 22.

MODEL PROCEDURE

For each multi-dose vial that you receive from a supplier or that you prepare, make a record of the:

- 1. Radiopharmaceutical;
- 2. Date of receipt or preparation;
- 3. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
- 4. Supplier or kit manufacturer;
- 5. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual),
 - b. Date and time dosage was drawn and measured,
 - c. Calculated volume that is needed for the prescribed dosage,
 - d. Measured activity in millicuries or microcuries, if using a dose calibrator,
 - e. Patient name and identification number if one has been assigned;
- 6. If discarded, the method of disposal and date; and
- 7. Initials of the individual who made the record.

Q.3

Measuring and Recording Molybdenum Concentration
(902 KAR 100:072, Section 32)

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration.

The model procedure for measuring molybdenum concentration is based on the use of a “molybdenum breakthrough pig.” Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution. If you will follow the model procedure, you may indicate on your application, “We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published Appendix Q.3 to “Medical Programs Licensing Guide, Revised April 2005.”

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:072, Section 32.

MODEL PROCEDURE

Each time a generator is eluted, make a record of the:

1. Date the generator was received;
2. Date and time of elution;
3. Measured Mo-99 activity in microcuries;
4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;
5. Measured Tc-99m activity in millicuries;
6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and check mark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. In conformance with 902 KAR 100:072, Section 32 (4), the licensee must notify the Cabinet if a leaking generator is detected.) (The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.)
7. Initials of the person who made the record.

Q.4

Measuring and Recording Strontium Concentration
(902 KAR 100:072, Section 32)

The regulations require that each licensee who uses a rubidium generator to prepare radiopharmaceuticals must test each elution or extraction for its strontium concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) Licensees may not administer radiopharmaceuticals that contain more than 0.02 microcurie of Sr-82 per millicurie of Rb-82, or 0.2 microcurie of Sr-85 per millicurie of Rb-85 at the time of administration.

This test is usually performed within the generating unit itself. In this case, follow the manufacturer's instructions. If testing external to the generating unit is required, use the procedure outlined in Q.3 of this appendix as a guide, remembering that the concentration limits and action levels will be different.

Q.5 Keeping an Inventory of Implant Sources (902 KAR 100:072, Section 39 and 100:042, Section 11)

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix Q.5 to 'Medical Programs Licensing Guide, Revised April 2005.'"

If you prefer, you may develop your own procedures for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of 902 KAR 100:072 Section 39.

MODEL PROCEDURE

1. Use a locking installed cabinet or safe to store all implant sources.
2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.
3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.
4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.
7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

APPENDIX R
MOBILE NUCLEAR MEDICINE REQUIREMENTS
(902 KAR 100:072, Section 28)

1. A complete application in accordance with 902 KAR 100:072.
2. A complete description of the services to be furnished at each location.
3. A statement signed by the management of each client granting approval for use of radioactive material at his/her facilities and clearly delineating the authority and responsibility of both the licensee and the client.
4. Confirmation that licensee personnel shall be on-site at the time that radiopharmaceuticals are delivered.
5. A description of your procedures for transporting the radioactive materials. Include shielding requirements and emergency procedures. Also indicate the area in the vehicle where the radioactive materials will be stored. (This location should be away from the passenger compartment.)
6. A description of the procedures for ensuring that radioactive materials, located in the coach, will be secured at all times.
7. A description of the training that will be provided to the drivers of the vehicles used for transporting the radioactive materials. (Note that their training should include all items specified in 902 KAR 100:165, Section 2 as well as instructions for handling spills and other emergencies.)
8. A description of the area in each facility where nuclear medicine procedures will be performed including waiting and staging areas, bathroom facilities, etc...
9. Confirmation that all areas of use will be surveyed prior to leaving each client's address to ensure compliance with the requirements of 902 KAR 100:019.
10. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check.
11. Because of the radiation safety problems associated with the use of radioactive gases, Xenon-133 has not been authorized for mobile nuclear medicine services.

APPENDIX S

GUIDANCE ON COMPLYING WITH 902 KAR 100:019 REQUIREMENTS Guide for the Preparation of Applications for Medical Programs

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Cabinet's regulations, the methods described in this guide will be used in the evaluation of applications for new licenses or license renewals and for evaluating compliance with 902 KAR 100:019.

1. RADIATION PROTECTION PROGRAMS

In 902 KAR 100:019, Section 2 each licensee is required to develop document, and implement a radiation protection program appropriate to the scope and extent of the activities conducted and to review at least annually the program content and its implementation. Further, 902 KAR 100:019, Section 2 requires that each licensee use engineering controls and procedures to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). In addition, 902 KAR 100:019, Section 30 provides the record keeping requirements for radiation protection programs.

The requirements in 902 KAR 100:019, Section 2 are consistent with the requirements for control of occupational exposures in 902 KAR 100:052 and 072. Radiation protection programs that have been established under the requirements of these regulations will be considered to be acceptable to meet the occupational ALARA requirements of 902 KAR 100:019, Section 2 when the program activities are limited to external occupational exposures. However licensees who handle unsealed radioactive materials that may cause internal exposure to members of the public will need to address potential internal as well as external doses to members of the general public from effluents to unrestricted areas. Additional guidance is published in NRC Regulatory Guide 8.37 "ALARA Levels for Effluents from Materials Facilities." Licensees should establish ALARA goals or objectives for effluents.

902 KAR 100:019 does not require that a numerical cost-benefit analysis (quantitative approach) be used to demonstrate ALARA. However, the Radiation Health Branch encourages medical licensees to use quantitative analyses in developing ALARA programs and procedures. If it can be performed readily, licensees should demonstrate through quantitative analysis that the cost and benefits associated with design, engineering controls, and operating procedures have been optimized in accordance with the ALARA principle. If a quantitative analysis cannot be readily performed, licensees should thoroughly evaluate any design or engineering controls that may need to be changed to keep operating procedures ALARA.

Examples of the type of ALARA optimization considerations appropriate to the conduct of medical use programs are presented in the National Council on Radiation

Protection and Measurement (NCRP) Report No. 107, "Implementation of the Principle of As Low As Is Reasonably Achievable (ALARA) for Medical and Dental Personnel,"* December 31, 1990. This NCRP report provides specific hypothetical examples of optimization decisions in achieving ALARA in nuclear medicine and radiation oncology.

*NCRP reports can be purchased by writing to NCRP Publications, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814.

2. INTERNAL DOSE METHODOLOGY

902 KAR 100:019 incorporates the dose methodology system developed by the International Commission on Radiological Protection (ICRP) which specifies radiation dose limits in terms of an "equivalent" whole body dose, taken to be the sum of individual organ committed doses weighted by the risk of biological effect for each of the organs irradiated. This effective dose equivalent concept is used to control the stochastic biological effects of exposure to ionizing radiation. Nonstochastic or threshold, biological effects are avoided by establishing dose limits for the committed dose received by an individual organ and for the exposure to the skin and to the lens of the eye (902 KAR 100:019, Section 3).

2.1 Units and Terms for Internal Exposure

902 KAR 100:019 uses the standard units of dose and activity and presents the corresponding values for the international system (SI). Records and reports required under 902 KAR 100:019 are to be maintained using the standard units.

The following table provides the conversions between the two systems of measurement:

Standard Units

(Activity) curie (Ci)	= 3.7×10^{10} disintegrations per second = 3.7×10^{10} Bq
(Absorbed dose) rad	= 100 ergs/gram (0.01 Gy)
(Dose equivalent) rem	= Quality factor x rad (0.01 Sv)

SI Units

(Activity) becquerel (Bq)	= 1 disintegration per second (2.7×10^{-13} Ci)
(Absorbed dose) gray (Gy)	= joule/kg (100 rads)
(Dose equivalent) sievert (Sv)	= Quality factor x grays (100 rems)

Exposure to airborne radioactivity at a level of 1 DAC for 1 year (2000 hours) would result in either a committed effective dose equivalent of 5 rems (50 mSv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. In order to show compliance with the occupational dose limit of 5 rems (50 mSv), a facility must consider the contributions of internal and external doses prior to calculating ventilation and gas clearance time.

Appendix M to the Licensing Guide provides model procedures for calculating worker doses from concentrations of gases in work areas and for calculating spilled gas clearance times. The procedure states that the MPC values for the radionuclide of interest should be used in the calculations. To implement the new regulation, the DAC value for the radionuclide of interest, in conjunction with the contribution of external dose, must be used instead of the MPC value. For example, consider the following simplified approach to determining required ventilation rates in an area where xenon-133 procedures will be performed:

Example:

A new room is being designed in an existing nuclear medicine department where xenon-133 ventilation studies will be performed. You are asked to calculate the minimum ventilation rates required to maintain compliance with the occupational dose limits.

1. Determine the highest dose to an individual from all external radiation for the previous 12 month period by reviewing personnel monitoring records (film, TLD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the DAC value for xenon-133 to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of 5 rems (50 mSv) and divide this number by 5 rems.

This yields the fraction of the dose limit of 5 rems that would still be permitted from internal sources. Multiplying this fraction times the DAC value yields a modified DAC. These DAC values are provided in 902 KAR 100:019, Section 44, Table 1, Column 3.

The annual external dose is 2 rems. The listed DAC value for xenon-133 is $1\text{E-}4$ mCi/mi. The modified DAC value should be based on 3 rems that could still be incurred from internal exposure.

3. Calculate the minimum ventilation rates for the room using the procedure provided in Appendix M to this Licensing Guide. In place of the MPC value stipulated in Appendix M, use the modified DAC value. In the example provided above, the modified DAC value ($6\text{E-}5$ mCi/ml) would be used instead of the MPC value for xenon-133.

The discussion and example presented in this section do not specifically address ALARA and the monitoring thresholds for internal doses as it relates to the summation of internal and external dose. However, it should be noted that modifications to ventilation rates can be a means to maintaining exposures ALARA. In addition, increased ventilation rates may negate the requirement to monitor internal dose and, as such, may eliminate the necessity to sum internal and external dose to show compliance with the occupational dose limits.

2.2 Occupational Dose Limits

902 KAR 100:019 applies the 5 rem (50 mSv) occupational dose limit as a whole body “effective” dose. This limit is the sum of the deep-dose equivalent from external sources and the committed effective dose equivalent to the organs exposed from the internal uptake of radionuclides, expressed as the total effective dose equivalent (902 KAR 100:019, Section 3). Additional guidance is provided in the NRC guide, “Monitoring Criteria and Methods To Calculate Occupational Doses,” on the methods to be used for determining these dose equivalents. Revision 1 of the guide, “Instructions for Recording and Reporting Occupational Radiation Exposure Data,” provides guidance on reporting the dose data on NRC Forms 4 and 5. 902 KAR 100:019 no longer contains provisions for an age proration 5(N-18).

2.3 Effective Dose Equivalent

The effective dose equivalent concept described above makes it possible to combine both the internal and external doses in assessing the overall risk of health effects to an individual. Prior to the adoption of 902 KAR 100:019 the activity concentration limits for intakes of a single radionuclide (in 902 KAR 100:025) were based on controlling the dose to the organ receiving the highest dose (“critical organ”). These concentration limits, however, were treated separately from the dose limits for external exposure. 902 KAR 100:019 dose methodology evaluates the doses to all major body organs, multiplies these doses by the appropriate organ weighting factors, and then sums the organ-weighted doses to obtain a whole body “risk-weighted effective dose.” The ALIs and DACs in 902 KAR 100:019, Section 44, therefore, reflect the doses to all principal organs that are irradiated, not just the one organ that receives the highest dose, as was done previously.

3. DECLARED PREGNANT WOMEN [Embryo/Fetus Dose Limits] (See 902 KAR 100:010 and 902 KAR 100:019, Section 9)

902 KAR 100:019 uses the term “declared pregnant woman” to mean a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

For declared pregnant women, the Cabinet limits the dose to the embryo/fetus to 0.5 rem (5 mSv) over the entire pregnancy. In addition, the licensee is required to make an effort to avoid substantial variation above a uniform monthly exposure rate (0.05 rem/month) (0.5 mSv/month). Declared pregnant women are not allowed to receive planned special exposures that involve whole body doses or maternal intakes that could result in exceeding the embryo/fetus dose limit. The radiation protection program should make provisions for instructing women workers about the special need to protect the embryo/fetus and to encourage them to promptly notify their employer if they become pregnant. The NRC guide “Radiation Dose to the Embryo/Fetus,” contains guidance on evaluating the dose to the embryo/fetus.

4. LEVELS IN UNRESTRICTED AREAS
(See 902 KAR 100:019, Sections 10 and 11)

902 KAR 100:019 uses the following terms, as defined in 902 KAR 100:010, with regard to areas with or without radiological restrictions:

“Controlled area” means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

“Entrance or access point” means a location through which an individual may gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

“Radiation area” means an area, accessible to individuals, in which there exists radiation at levels that an individual may receive in excess of 5 mrem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from a surface that the radiation penetrates.

“Restricted area” means an area, access to which is limited by the licensee for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. A restricted area shall not include areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

“Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

“Unrestricted area” means an area, access to which is not limited nor controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive material.

The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted to 2 mrem (20 mSv) in any 1 hour from external sources and to 100 mrem (1 mSv) in a year total effective dose equivalent for individual members of the public. Depending on how the licensee’s areas are controlled and monitored, hallway areas outside patient therapy rooms and diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

5. NVLAP PROCESSORS
(See 902 KAR 100:019, Section 12)

Personnel dosimeters that require processing to determine the dose to compare to the 902 KAR 100:019 dose limits must be processed and evaluated by a dosimetry processor that is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP).

6. CONTROL OF LABORATORIES
(See 902 KAR 100:019, Sections 2, 17, 21, 22 and 24)

Access to laboratories using radionuclides as well as the work practices in these laboratories, need to be controlled. Controlling access to radionuclide laboratories is accomplished by posting the entrance door and locking all accessible entrances to the laboratory when an authorized user, or an individual under the supervision of an authorized user, is not present. An acceptable alternative is to provide lockable storage facilities within the laboratory. In 902 KAR 100:019, Section 24(5), posting is required for each area or room in which there is used or stored a quantity of licensed material exceeding 10 times the quantity in 902 KAR 100:030. Some of the 902 KAR 100:030 quantities will be changed. Appendix G to the Medical Licensing Guide provides model rules for safe use of radiopharmaceuticals that can be used for radionuclide laboratories, and Appendix H provides model spill procedures.

7. POSTING AND CONTROLLING ACCESS TO PATIENT ROOMS (See 902 KAR 100:019, Section 25(2))

When patients have received therapeutic administrations of radionuclides or therapeutic applications of sealed sources, the criteria for exceptions to posting requirements specified in 902 KAR 100:019, Section 25 will likely be exceeded. Dose rates from therapy patients can often exceed 5 mrem (50 mSv) per hour at 1 meter from the patient. Under these conditions, the entrance to the patient's room must be posted and access to the area controlled. Access can be controlled by routine surveillance and by posting instructions for hospital personnel and visitors at the entrance to the patient's room. Examples of such instructions can be found in Exhibit 9 of the licensing guide. Systems such as remote TV surveillance, electronic eye, or personnel entry detection devices are considered acceptable for monitoring personnel access to the patient's room.

Note that 902 KAR 100:019, Section 25 allows exceptions to the posting requirements if specific conditions are met. Licensees should review 902 KAR 100:019, Sections 24 and 25 for posting requirements since some of the posting language has changed.

8. EXEMPTIONS TO LABELING REQUIREMENTS (See 902 KAR 100:019, Section 27)

Licensees are not required to label containers holding licensed material in quantities less than the quantities listed in 902 KAR 100:030. For iodine 125, carbon-14, and sulfur-35, the quantities below which labeling is not required are 1 uCi, 1000 uCi, and 100 uCi, respectively. In addition, licensees are not required to label containers holding licensed material in concentrations less than those specified in Table 3 of Section 44 to 902 KAR 100:019. For iodine-125, carbon-14, and sulfur-35, the exempt concentrations are 2E-5 uCi/ml, 3E-4 uCi/ml, and 1E-3 uCi/ml, respectively.

9. PROCEDURES FOR RECEIVING AND OPENING PACKAGES (See 902 KAR 100:019, Section 28(3) and (4))

902 KAR 100:019, Section 28 modifies the Type A package quantity limits affecting package opening procedures, monitoring required for radioactive contamination on external surfaces of a package, and surface contamination levels requiring notification of the Radiation Health Branch as follows: Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in 902 KAR 100:070 (e.g., more than 13.5 curies of molybdenum-99; 216 curies of technetium-99m; 13.5 curies of iodine-131, cesium-137, or iridium-192; or more than 54.1 curies of iodine-125). All shipping packages received, known to containing radioactive material or if there is evidence of damage to the package. Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours, or within 3 hours from the beginning of the next working day if received after working hours, in accordance with the requirements of 902 KAR 100:019, Section 28. The Radiation Health Branch and the final delivery carrier must be notified immediately if removable contamination or the external radiation levels exceed the limits of 902 KAR 100:070. Note that these Appendix S procedures for receiving and opening packages do not exempt packages containing less than Type A quantities of radioactive material from removable contamination surveys as did 902 KAR 100:035 and Appendix F to this licensing guide. Therefore, it may be necessary for a licensee to revise current package opening procedures to reflect the changes in 902 KAR 100:019.

10. EFFLUENT RELEASES TO SEWER

902 KAR 100:021, Section 3 allows licensees, under certain quantity release constraints, to discharge licensed material into sanitary sewers if the material is readily soluble in water or if the material is readily dispersible biological material. Dispersible in this context means able to be distributed as particles, more or less evenly throughout a medium, such as a sewer system. In practical terms, biological material should be divided finely enough so as to mix readily with a water stream and continue to disperse rather than to reconcentrate. This provision allows continuation of the practice of discharging readily dispersible biological materials such as ground-up animal carcasses. The prohibition of the discharge to sanitary sewer systems of non-biological insoluble materials by the regulation was designed to minimize the accumulation of insoluble material in the sewer system, treatment plant, and in sewage sludge. Licensees should note that the monthly average concentrations of radionuclides allowed to be released to sanitary sewers under 902 KAR 100:021 and Table 3 of 902 KAR 100:019, Section 44 are, generally 10 times more restrictive than the monthly average concentrations that have been allowed to be released into sanitary sewer systems under 902 KAR 100:025.

APPENDIX T

WRITTEN DIRECTIVES (902 KAR 100:072, Sections 13 & 14)

A written directive must be dated and signed by an authorized user before the administration of I-131 greater than 30 microcuries, any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record.

A written directive must be prepared within forty-eight (48) hours of the oral directive.

A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record.

A revised written directive must be signed by the authorized user within forty-eight (48) hours of the oral revision.

The licensee shall retain a copy of the written directive for three (3) years.

For any administration requiring a written directive, the licensee shall develop, implement and maintain written procedures to provide high confidence that:

- The patient's or human research subject's identity is verified before each administration, and
- Each administration is in accordance with the written directive

A licensee shall retain a copy of the written procedures for the duration of the license.

The following are elements for consideration when developing written procedures. Some may or may not apply to your facility. The requirements of 902 KAR 100:072 sections 13 and 14 should be carefully reviewed and incorporated into any written procedures.

Elements pertinent to all therapies requiring a written directive

Prior to administration, a written directive issued by an authorized user will be prepared. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

1. Patient's name
2. Patient identification number, if available
3. Radiopharmaceutical
4. Dosage
5. Route of administration
6. The type of procedure desired
7. Date
8. Signature of authorized user

Prior to administration, the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the administration will complete the verification. Verification of identity must include at least two of the following methods:

1. The patient shall be asked to state and spell their name.
2. The patient shall be asked to state their birth date.
3. The patient shall be asked to state their social security number.
4. The patient shall be asked to state their address.
5. The patient shall be asked for identification, i.e. driver's license.
6. The patient's wrist identification band shall be checked for name and patient number.
7. For patients unable to respond, an accompanying relative or friend may attest to the patient's identity. Record name and relationship of same.

If the information obtained from any two of these methods does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification is obtained.

Oral directives are permissible only when a patient's medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is documented in writing as soon as possible in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. (See 902 KAR 100:072, Sections 15 & 16)

An annual review should be conducted to ensure compliance and effectiveness.

Elements pertinent to the use of I-131 or any other therapeutic dosage of unsealed radioactive material

Each administration must be in accordance with the written directive. The physician or nuclear medicine technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

Each administration must have a written protocol. A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures performed which require written directives. A procedure, which requires a written directive, shall not be initiated until a written protocol approved by an authorized user is available. The nuclear medicine physicians and technologists shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them. The protocol shall contain the following elements:

1. Pharmaceutical
2. Radionuclide
3. Routine dosage
4. Route of administration
5. Indications
6. Contraindications

Any change in protocol shall be approved by an authorized user before that change is implemented and always before the change is incorporated into the procedure manual. Each person who prepares and administers radiopharmaceuticals shall be instructed in the change before it is implemented or incorporated into the procedure manual.

Following administration of the radiopharmaceutical dose, a dated and signed written note is entered into the patient's record documenting the administration and dosage.

Elements pertinent to a therapeutic dose of radiation from radioactive material

Each administration must be in accordance with the written directive. A qualified individual shall read the written directive before preparing or administering the brachytherapy dose. A qualified individual includes radiation therapy physicist, oncology physicians, dosimetrists, or radiation therapy technologists. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The brachytherapy dose shall not be administered until the intent of the written directive is thoroughly understood by the personnel administering the dose. The specific details of the treatment plan shall be verified with the written directive by a qualified individual.

Radiographs or other comparable images (e.g., CT images) made with either the brachytherapy sources or non-radioactive “dummy” sources in place should be used as the basis for verifying the positions of the sources and calculating the treatment time. The use of dummy sources are preferred over active ones whenever possible. It is recognized that such images may not be necessary in certain procedures in which applicators are used, provided the source positions are known prior to inserting the active sources and calculating the treatment time.

After insertion of either permanent or temporary brachytherapy sources an authorized user will promptly record the actual loading sequence of the radioactive sources implanted and sign or initial the patient’s chart or other appropriate record.

During the implant or loading procedure, the end of any tubing containing radioactive sources must be positioned and secured in such a way as to minimize the possibility of accidental dislodgment. The patient is observed frequently by nursing personnel to verify that the sources remain in position as loaded for the duration of the treatment period.

Before the total prescribed brachytherapy dose has been delivered, an authorized user, or a qualified individual under the supervision of an authorized user, (other than the person who made the original calculations, if possible), shall check the dose calculations. Manual dose calculations should be checked for arithmetic errors; appropriate transfer of data from the written directive, plan of treatment, tables and graphs; appropriate use of nomograms (when applicable) and appropriate use of all pertinent data in the calculations.

Computer generated dose calculations shall be checked by examining the computer printout to verify that the correct data for the patient was used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Alternatively, the brachytherapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer generated outputs (or vice versa), particular emphasis should be placed on verifying the correct

output from one type of calculation (e.g., computer) to be used as an input in another type of calculations (e.g., manual).

NOTE: If the authorized user determines that delaying treatment in order to perform checks of dose calculation would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations shall be performed within two working days of completion of the brachytherapy treatment.

An authorized user must date and sign a written record in the patient's chart after insertion of the brachytherapy source but prior to completion of the procedure. The written record shall include the radionuclide, treatment site, total source strength and exposure time (or equivalently, the total dose).

Acceptance testing will be done by a qualified individual on each treatment planning of dose calculating computer program that can be used for brachytherapy dose calculations. Acceptance testing will be performed before the first use of a computer program for brachytherapy dose calculations. A written record shall be kept documenting the results of the acceptance tests.

Subsequent to the loading of brachytherapy sources, an authorized user or other qualified individual shall verify that the written directive was followed in terms of the number of sources implanted, the source strengths and the source positions. The treatment time will be reaffirmed at this time. In some instances, the authorized user may determine that radiographic procedures are required to confirm proper source positioning.

EXHIBIT 3

Radioactive Spill Report

The spill occurred at ____:____^{am} pm on ____/____/____ in room _____.

Instrument used to check for personnel contamination:

Meter model: _____ Meter SN: _____ Probe model: _____ Probe SN: _____

Personnel present

Personnel contamination results*

_____	_____
_____	_____
_____	_____
_____	_____

* On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a post cleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:

____ mCi of ____ as _____

____ mCi of ____ as _____

____ mCi of ____ as _____

Give a brief description of the accident:

Give a brief description of follow up actions taken to prevent recurrence:

Name: _____ Date: _____

EXHIBIT 4

Radioactive Spill Contamination Survey

The spill occurred at ____:____^{am} pm on ____/____/____ in room _____.

Decontamination completed at ____:____^{am} pm

LOCATION	PRE-CLEAN	POST CLEAN	
	(mR/hr)	(mR/hr)	dpm/100 cm ²

Name:_____

EXHIBIT 5

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P. O. No. _____ Survey Date _____ Time _____
Surveyor _____
2. CONDITION OF PACKAGE:
_____ OK _____ Punctured _____ Status _____ Wet
_____ Crushed _____ Other _____
3. RADIATION UNITS OF LABEL: _____ Units (mR/hr)
4. MEASURED RADIATION LEVELS:
 - a. Package surface _____ mR/hr
5. DO PACKING SLIP AND VIAL CONTENTS AGREE:
 - a. Radionuclide _____ yes _____ no, difference _____
 - b. Amount _____ yes _____ no, difference _____
 - c. Chem Form _____ yes _____ no, difference _____
6. WIPE RESULTS FROM:
 - a. Outer _____ CPM = _____ DPM
 $eff = (\quad)$
 - b. Final source container _____ CPM = _____ DPM
7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mR/hr, CPM
8. DISPOSITION OF PACKAGE AFTER INSPECTION _____
9. SURVEY METER _____
10. INSTRUMENT USE TO COUNT WIPES _____
11. IF CABINET FOR HEALTH SERVICES/CARRIER NOTIFICATION
REQUIRED, GIVE TIME, DATE, AND PERSON NOTIFIED.

Signature _____ Date _____

EXHIBIT 6
NURSING INSTRUCTIONS FOR PATIENTS GIVEN RADIOISOTOPE THERAPY
REQUIRING A WRITTEN DIRECTIVE (RADIOPHARMACEUTICAL AND
PERMANENT IMPLANT THERAPIES)

Patient's Name: _____ Date _____

Room No. _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

	Exposure Rates in mR/hr	
Date	3 feet from bed	10 feet from bed

Comply with all checked items:

- ___ 1. Visiting time permitted: _____
- ___ 2. Visitors must remain _____ from patient.
- ___ 3. Patient may not leave room.
- ___ 4. Visitors under 18 are not permitted.
- ___ 5. Pregnant visitors are not permitted.
- ___ 6. Film or TLD badges must be worn.
- ___ 7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.
- ___ 8. Tag the following objects and fill out the tag:

door _____ chart _____ bed _____ wrist
- ___ 9. Disposable gloves must be worn while attending patient.
- ___ 10. Patient must use disposable utensils.
- ___ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.
- ___ 12. Smoking is not permitted.
- ___ 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
- ___ 14. Other instructions.

In case of an emergency contact:

<u>RSO</u> Name _____	On-duty/Off-duty Telephone Numbers _____
--------------------------	--

EXHIBIT 7

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY OVER 33 MILLICURIES

Patient: _____ Room: _____ Date _____

PREPARATION

- _____ Schedule a private room, with private sanitary facilities and without carpet, in a low traffic area.
- _____ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
- _____ Prepare labeled boxes for used linen, disposable waste, and non-disposable contaminated items.
- _____ Prepare urine collection containers if urine will be collected.
- _____ Stock room with disposable gloves, absorbent paper, and "radioactive waste" labels.
- _____ Mark a visitors' "safe line" on the floor.
- _____ Order disposable table service.
- _____ Notify housekeeping to not clean the room until further notice.
- _____ Brief the nursing staff on radiation safety measures.
- _____ Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION

- _____ Clear the room of unneeded personnel.
- _____ Brief the patient on the clinical procedure.
- _____ Administer the dosage.
- _____ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
- _____ Post the room with a "Radioactive Materials" sign.

FOLLOW-UP

- _____ Measure the thyroid burden of all personnel who were present for the administration.
- _____ Pick up waste for decay-in-storage or decontamination.
- _____ Release the patient.
- _____ Decontaminate and survey the room. Remove the "Radioactive Materials" sign.
- _____ Call the Housekeeping Office to clean the room.

EXHIBIT 8

RADIATION SAFETY CHECKLIST FOR TEMPORARY IMPLANT THERAPY

Patient: _____ Room _____ Date: _____

PREPARATION

- _____ Schedule a private room in a low traffic area.
- _____ Mark a visitors' "safe line" on the floor.
- _____ Brief the nursing staff on radiation safety measures.
- _____ Supply the nursing staff with personnel radiation dosimeters.

IMPLANT

- _____ Clear the room of unneeded personnel.
- _____ Brief the patient on the clinical procedure.
- _____ Insert the implant.
- _____ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
- _____ Post the room with a "Radioactive Materials" sign.

FOLLOW-UP

- _____ Make a radiation survey of the patient to assure that all sources have been removed.
- _____ Count the number of sources removed from the patient to assure that all sources have been removed.
- _____ Remove the "Radioactive Materials" sign.

EXHIBIT 9
NURSING INSTRUCTIONS FOR PATIENTS TREATED
WITH TEMPORARY IMPLANT SOURCES

Patient's Name: _____
Phone: _____
Patient Number: _____
Pager: _____ Patient Room: _____
Dose: _____ mCi of _____ as _____ individual sources was loaded on ____/____/____.
am
Sources will be removed at approximately ____:____pm on ____/____/____.

RADIATION EXPOSURE RATES

Unrestricted areas: Door _____ mR/hr; room ____--____ mR/hr; room ____--____ mR/hr

Patient supine in bed or _____

Date	Time	Bedside	3 ft from bed	Door
____/____/____	am ____:____pm	____mR/hr	____mR/h	____mR/hr ____mR/hr

Release certification: Patient may not be released from the hospital until the following certification is signed and dated by the RSO or the attending physician.

I have removed and counted _____ individual sources from this patient. A low-range GM survey of the patient failed to indicate any remaining sources in the patient.

Signature: _____ Date ____/____/____

INSTRUCTIONS

Visitor Restrictions:

- _____ No visitors under 18 or pregnant.
- _____ Minutes each day maximum for each visitor.
- _____ Visitors must stay behind line on floor at all times.

Nursing Restrictions:

- _____ Patient is restricted to room.
- _____ Patient is restricted to bed.
- _____ Patient must not move.
- _____ No nurses who are pregnant may render care.
- _____ Minutes each day per nurse in the room.

Patient Care:

- _____ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do Not share. Call RSO for additional monitors if needed.
- _____ If a source appears dislodged, call the attending physician and the RSO immediately.
- _____ Omit bed bath.
- _____ No perineal care. Pad may be changed as necessary.
- _____ Save surgical dressings for disposal by attending physician or RSO.
- _____ See special oral hygiene care instructions.

In case of emergency, or if you have a question, call:

RSO: _____ Work: _____ Home: _____
Pager: _____
MD _____ Work: _____ Home: _____
Pager: _____

EXHIBIT 10
ANNUAL MEDICAL LICENSEE RADIOACTIVE MATERIAL PROGRAM
AUDIT FOR NUCLEAR MEDICINE

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Date of this audit: _____ Date of last audit: _____

Auditor: _____ Date: _____

Management review: _____ Date: _____

AUDIT HISTORY

A. Were previous audits conducted annually (100:019, Sec 2)? ()Y ()N

B. Were records of previous audits maintained for 3 years (100:019, Sec 2)? ()Y ()N

C. Were any deficiencies identified during previous audits? ()Y ()N

Deficiencies noted: _____

D. Were corrective actions taken? (Look for repeated deficiencies) ()Y ()N

ORGANIZATION AND SCOPE OF PROGRAM

A. Radiation Safety Officer

1. If the RSO was changed, was license amended (100:072, Sec 5)? ()Y ()N

2. Does new RSO meet training requirements (100:072, Sec 65)? ()Y ()N

3. Is RSO fulfilling his/her duties (100:072, Sec 10)? ()Y ()N

B. All users authorized by the license or licensee's management (Cabinet for Health & Family Services notified within 30 days of adding an Authorized User)? ()Y ()N

C. Cabinet for Health & Family Services notified within 30 days of permanent discontinued performance of duties under the license for the RSO, authorized user, teletherapy physics, or authorized nuclear pharmacist (100:072, Sec 6)? ()Y ()N

D. Are all locations of use listed on license (license condition)? ()Y ()N

E. If places of use changed, was the license amended (100:072, Sec 5)? ()Y ()N

F. If control of license was transferred or bankruptcy filed, was Cabinet prior consent obtained or notification made (100:040, Sec 11)? ()Y ()N

WRITTEN DIRECTIVES (100:072, Sec 13 & 14)

- A. Have procedures for administrations requiring a written directive been reviewed? ()Y ()N

RADIATION SAFETY COMMITTEE (RSC) (100:072, Sec 10)

- A. Has required membership of RSO, an authorized user of each type of use permitted by the license, a representative from nursing, and a representative from management? ()Y ()N

LICENSED MATERIAL

- A. Isotopes, chemical forms, quantity and use as authorized (license condition)? ()Y ()N
- B. Calibration and references sources authorized by 100:072, Sec 23? ()Y ()N
- C. Is all unsealed material used under 100:072, Sec 30, 31, and 33 obtained from a properly licensed organization AND/OR prepared by a physician user, or an individual under the supervision of an authorized nuclear pharmacist or physician user? ()Y ()N

TRAINING AND INSTRUCTION TO WORKERS

- A. Have workers been provided with required instructions (100:0165, Sec 2)? ()Y ()N
- B. Is annual retraining performed (license condition)? ()Y ()N
- C. Are initial and annual training records maintained for each individual ? ()Y ()N

DOSE CALIBRATOR (100:072, Sec 20)

- A. Calibrated in accordance with nationally recognized standards (see below) or the manufacturer's instructions. ()Y ()N

EXAMPLE OF NATIONALLY RECOGNIZED STANDARDS

- A. Accuracy, linearity, and geometry dependence performed before initial use, following repair, and relocation of each dose calibrator? ()Y ()N
- B. Constancy performed for each day the dose calibrator is used? ()Y ()N
1. Record maintained 3 years and includes:
- a. Model & serial number of dose calibrator?
 - b. Identity & calculated activity of check source?
 - c. Date of the check?
 - d. Activity measured within 10%?
 - e. Instrument settings?
 - f. Initials of individual performing the check? ()Y ()N
- C. Linearity test performed at intervals not to exceed 3 months? ()Y ()N
1. Records maintained 3 years and includes:
- a. Model & serial number of dose calibrator?
 - b. Identity & calculated activity of check source?
 - c. Date of the test?
 - d. Activity measured within 10%?
 - e. Signature of individual performing the test? ()Y ()N
2. Linearity performed from 30 μ Ci to highest dose administered? ()Y ()N
- D. Accuracy test performed at intervals not to exceed 12 months? ()Y ()N
1. Record maintained 3 years and includes:
- a. Model & serial number of dose calibrator?
 - b. Model & serial number for each source?
 - c. Date of the test?
 - d. Results within 10%?
 - e. Instrument settings?
 - f. Signature of individual performing the test? ()Y ()N
- E. Geometry test record maintained until dose calibrator no longer used and includes:
- 1. Model & serial number of dose calibrator?
 - 2. Configuration & calibrated activity of the source measured?
 - 3. Date of the test?
 - 4. Activity of the source measured within 10%?
 - 5. Measured activity & instrument setting for each volume measured?
 - 6. Signature of individual performing the test? ()Y ()N
- F. Dose calibrator repaired or replaced if accuracy or constancy error exceeds 10%? ()Y ()N
- G. Dosage readings mathematically corrected for geometry or linearity errors <10%? ()Y ()N

ASSAY OF RADIOPHARMACEUTICAL DOSES (100:072, Sec 22)

- A. Each dose determined and recorded prior to medical use? ()Y ()N
- B. Records maintained 3 years and include:
1. Radiopharmaceutical?
 2. Patient's name?
 3. Prescribed dosage?
 4. Activity at time of assay?
 5. Date and time of dosage determination?
 6. Name of person who performed assay? ()Y ()N

GENERATORS (100:072, Sec 32)

- A. First elute after receipt of a generator tested for radionuclide contaminant concentration? ()Y ()N
- B. No radiopharmaceuticals administered with contaminant concentrations over the limits specified in 902 KAR 100:072, Section 32(1)? ()Y ()N
- C. Records maintained and include required information? ()Y ()N
- D. Reported each occurrence of contamination concentration exceeding limits? ()Y ()N
- E. Receipt, transfer, and disposal records for each generator maintained? ()Y ()N
- F. Columns held for decay for 10 half lives before disposal? ()Y ()N
- G. If generators are returned to vender, are DOT requirements met? ()Y ()N

RADIATION PROTECTION

- A. Safe use of radiopharmaceuticals (license condition):
1. Protective clothing and gloves worn? ()Y ()N
 2. No eating or drinking in use and storage areas? ()Y ()N
 3. Proper dosimetry worn? ()Y ()N
 4. Radioactive waste disposed in proper receptacles? ()Y ()N
 5. Remote handling devices (tongs) available and used? ()Y ()N
 6. Syringe shields and vial shields used? ()Y ()N
- B. Leak tests and inventories (100:072, Sec 24):
1. Leak test performed on sealed sources at intervals not to exceed 6 months? ()Y ()N
 2. Leak test records maintained 3 years and includes:

- a. Model & serial number of each source?
 - b. Identity of each source radionuclide?
 - c. Estimated activity of each source?
 - d. Results of the test?
 - e. Date of test?
 - f. Name of the individual who performed the test? ()Y ()N
3. Inventory of sealed sources performed semi-annually? ()Y ()N
4. Inventory records maintained 3 years and include:
- a. Model and serial number of each source?
 - b. Identity of each source radionuclide?
 - c. Nominal activity of each source?
 - d. Location of each source?
 - e. Name of the individual who performed the inventory? ()Y ()N

RADIATION SURVEY INSTRUMENTS (100:072, Sec 21)

- A. Survey instruments used to show compliance with 100:019? ()Y ()N
- B. Appropriate survey instruments possessed? ()Y ()N
- C. Survey instruments calibrated before first use, annually, and after repairs (100:072, Sec 21)? ()Y ()N
- D. Dedicated check source reading noted on survey instruments (100:072, Sec 21)? ()Y ()N

RADIATION SURVEYS (100:072, Sec 21)

- A. Instrument survey performed daily where unsealed radioactive material requiring a written directive were prepared for use or administered? ()Y ()N
1. Records maintained for 3 years and includes:
- a. Date of survey?
 - b. Results of the survey?
 - c. Instrument used to conduct the survey?
 - d. Name of person who performed the survey? ()Y ()N

PUBLIC DOSE (100:019)

- A. Licensed material used and stored in a manner to keep doses below 100 mRem in a year (100:019, Sec 10)? ()Y ()N
- B. Have surveys or evaluations been performed per 100:019, Sec 11? ()Y ()N
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation? ()Y ()N
- D. Do unrestricted area radiation levels exceed 2 mRem in any one hour? ()Y ()N

- E. Licensed material used or stored in a manner that would prevent unauthorized access or removal (100:019, Sec 21 & 22)? ()Y ()N
- F. Records maintained and include required information (100:019, Sec 31)? ()Y ()N

RADIOACTIVE WASTE

- A. Decay-in-storage (100:072, Sec 29)
1. Waste held for 10 half-lives? ()Y ()N
 2. Labels removed or obliterated? ()Y ()N
 3. Monitored at surface of container before disposal as ordinary trash? ()Y ()N
 4. Records maintained for 3 years and includes:
 - a. Date of the disposal?
 - b. Date waste was put in storage?
 - c. Radionuclide disposed?
 - d. Model & serial number of survey instrument used?
 - e. Background dose rate?
 - f. Dose rate measured at the surface of each container?
 - e. Name of individual performing the disposal? ()Y ()N
- B. Waste storage
1. Protected from elements and fire? ()Y ()N
 2. Control of waste maintained (100:019, Sec 21)? ()Y ()N
 3. Containers properly labeled and area properly posted (100:019, Sec 24 & 26)? ()Y ()N
 4. Package integrity adequately maintained? ()Y ()N
- C. Waste disposal
1. Waste transferred to authorized individuals (100:021, Sec 1)? ()Y ()N
 2. Name of organization: _____
 3. Records maintained (100:021, Sec 11)? ()Y ()N

RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- A. Written package opening procedures established and followed (100:019, Sec 28)? ()Y ()N
- B. All incoming packages with a DOT label wiped, unless exempt (100:019, Sec 28)? ()Y ()N
- C. Incoming packages surveyed (100:019, Sec 28)? ()Y ()N
- D. Records maintained and include required information (100:040, Sec 14)? ()Y ()N

- E. Transfer(s) performed per 100:040, Sec 12? ()Y ()N
- F. All radioactive material surveyed before shipping or transfer (100:070, Sec 14)? ()Y ()N
- G. Records of surveys and receipt/transfer maintained (100:019, Sec 31, 100:070, Sec 16)? ()Y ()N
- H. Package receipt/distribution activities evaluated for compliance with 100:019, Sec 11? ()Y ()N

TRANSPORTATION (100:070 and Code of Federal Regulations, parts 171-189)

- A. Returned radiopharmacy doses or sealed sources? ()Y ()N
1. Licensee assumes shipping responsibilities? ()Y ()N
2. If NO, is the arrangements made between licensee and radiopharmacy for shipping responsibilities on file? ()Y ()N

POSTING AND LABELING

- A. Kentucky Form KR-441, "Notice to Employees" is posted (100:165, Sec 1)? ()Y ()N
- B. 902 KAR 100:019 and 100:165, emergency and operating procedures, and license documents are posted, or a notice indicating where documents can be examined is posted (100:165, Sec 1)? ()Y ()N
- C. Posting for radiation or high radiation areas (100:019, Sec 24)? ()Y ()N
- D. Posting for radioactive material use and storage (100:019, Sec 24)? ()Y ()N

PERSONNEL RADIATION PROTECTION

- A. Exposure evaluation performed)? ()Y ()N
- B. External Dosimetry
1. Monitors workers per 100:019, Sec 13? ()Y ()N
2. Supplier _____
3. Exchange frequency _____
4. Supplier NVLAP approved (100:019, Sec 12)? ()Y ()N
5. Dosimeters exchanged at required frequency? ()Y ()N
- C. Internal Dosimetry
1. Monitors workers per 100:019, Sec 13? ()Y ()N
2. Monitoring program implemented (including bioassays) (100:072, Sec 35)? ()Y ()N

E. Reports

1. Reviewed by _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals (100:019, Sec 32)? ()Y ()N
4. Maximum exposures TEDE _____ Extremity _____
5. Internal and external doses summed (100:019, Sec 19)? ()Y ()N
6. Worker declared her pregnancy in writing during audit period? ()Y ()N
If yes, in compliance with 100:019, Sec 9 and records maintained? ()Y ()N
7. Records of exposures, surveys, monitoring, and evaluations maintained (100:019, Sec 12 & 34)? ()Y ()N

NOTIFICATION AND REPORTS

- A. In compliance with 100:0165, Sec 3, and 100:019, Sec 35, (reports to individuals, public and occupational, monitored to show compliance with 100:019)? ()Y ()N
- B. In compliance with 100:019, Sec 28 (theft and loss)? ()Y ()N
- C. In compliance with 100:019, Sec 39 (incidents)? ()Y ()N
- D. In compliance with 100:019, Sec 40 (overexposures and high radiation levels)? ()Y ()N

MEDICAL EVENTS (100:072, Sec 15, 16 & 17)

1. Event date _____ Information source _____
 2. Notifications made to:
 - a. Cabinet for Health & Family Services ()Y ()N
 - b. Patient ()Y ()N
 - c. Referring Physician ()Y ()N
 - d. In writing / By telephone ()Y ()N
 3. Written Reports
 - a. Submitted to Cabinet for Health & Family Services within 15 days? ()Y ()N
 - b. Copy to patient upon request? ()Y ()N
- Records maintained? ()Y ()N

Recordable events:

- | | |
|-----------------------------|-----------|
| 1. Investigation performed? | ()Y ()N |
| 2. Cause identified? | ()Y ()N |
| 3. Corrective action taken? | ()Y ()N |

AUDITS AND FINDINGS

A. Summary of findings: _____

B. Corrective and preventive actions: _____
